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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,050	04/05/00	MANGEL	A PU3375USW

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EXAMINER

SPIVACK, P

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/529,050**

Applicant(s)

**Mangel et al.**

Examiner  
**Phyllis G. Spivack**

Group Art Unit  
**1614**



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 5-8 and 11-18 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 5-8 and 11-18 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicants' Preliminary Amendment filed April 5, 2000, Paper No. 3, is acknowledged. Claims 1-4, 9 and 10 are canceled. New claims 11-18 are presented. Accordingly, claims 5-8 and 11-18 are now under consideration.

An Information Disclosure Statement filed April 5, 2000, Paper No. 4, is further acknowledged and has been reviewed.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to for the following informality: In claims 14 and 18 "cilansetron" is incorrectly spelled.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 8, 11, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kon et al., U.S. Patent No. 5,017,573.

Kon teaches the administration of indazole-3-carboxylic acid derivatives that are selective antagonists of 5-HT<sub>3</sub> receptors for use in the treatment of irritable bowel syndrome (IBS). See column 18, lines 43-44. Granisetron and indisetron are examples. The claims differ in that Kon does not distinguish among those patients who are nonconstipated female IBS patients, diarrhea-

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dominant female IBS patients and alternating constipation/diarrhea IBS patients. However, one skilled in the gastroenterology art would have been motivated to administer an indazole-3-carboxylic acid derivative as disclosed by Kon in each type of irritable bowel disease. Such would have been obvious in the absence of evidence to the contrary because Kon teaches the efficacy of these compounds for both the diarrhea and constipation that characterize IBS. It is well established in the art that women develop this condition at 3 times the rate of occurrence of men.

Claims 5-8 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardhan et al., Gastroenterology.

Bardhan teaches the administration of the highly selective antagonist of the 5-HT<sub>3</sub> receptor, alosetron (as the hydrochloride), for use in the treatment of patients with irritable bowel syndrome (IBS). Bardhan fails to distinguish among the patients with altered bowel habits as to whether constipation or diarrhea is dominant. Further, Bardhan does not include other 5-HT<sub>3</sub> receptor antagonists in his teaching. However, one skilled in the gastroenterology art would have been motivated to administer other 5-HT<sub>3</sub> receptor antagonists, such as ondansetron, in view of the teachings of Bardhan. Such would have been obvious in the absence of evidence to the contrary because compounds of such close structural similarity as alosetron and ondansetron would have reasonably been expected to exhibit the same utility in the treatment of IBS. It is well established in the prior art that women are more commonly affected than men. Further, the recitation "altered bowel habits" would have reasonably encompassed both constipation and diarrhea in patients suffering from IBS.

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No claim is allowed.

A list of co-pending or related cases is requested when Applicants respond to this Office Action.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

August 25, 2000

*Phyllis Spivack*

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**